

EXHIBIT DD

CORONAVIRUS

The Lancet retracts large study on hydroxychloroquine

"A first-year statistics major could tell you about major flaws in the design of the analysis," one expert said.



— A large study suggesting hydroxychloroquine does not benefit COVID-19 patients, and may even increase deaths, has been retracted. But that doesn't mean hydroxychloroquine does – or does not – work.

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By Erika Edwards

The medical journal The Lancet on Thursday retracted a [large study on the use of hydroxychloroquine](#) to treat COVID-19 because of potential flaws in the research data. The study,

published two weeks ago, found no benefit to the drug – and suggested its use may even increase the risk of death.

Thursday's retraction doesn't mean that the drug is helpful – or harmful – with respect to the coronavirus. Rather, the study authors were unable to confirm that the data set was accurate.

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Researchers from Brigham and Women's Hospital in Boston had worked with a health care analytics company, Surgisphere Corp., on the study.

"After publication of our Lancet article, several concerns were raised with respect to the veracity of the data and analyses conducted by Surgisphere Corporation," the study authors wrote in their [retraction](#).

The study authors said they launched an independent review to confirm the findings, but said the company would not provide access to all of the data.

"Based on this development, we can no longer vouch for the veracity of the primary data sources," the authors wrote.

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A [statement on the Surgisphere](#) website defended its data registry, adding the company had "clearly outlined the limitations of an observational study that cannot fully control for unobservable confounding measures."

The study itself was huge, including, it claimed, data from 96,000 COVID-19 patients from 671 hospitals on six continents. The findings suggested hydroxychloroquine did not benefit patients and was actually associated with an increased risk of dying in the hospital.

The large number of patients raised important questions among outside experts.

"The amount of patients that were included in a given country or given continent was almost more or a very high proportion of the total number reported in that geographic area, as if they were including more cases than possible," said Dr. Daniel Culver, a pulmonary and critical care expert at the Cleveland Clinic who was not involved with the research.

Culver said there were also concerns about whether the drug was even available for COVID-19 patients in some areas where it was reported to have been used.

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"It's not that the analysis itself was done wrong," Culver said. "It's just they don't have the data in that database to account for what they need to account for."

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The drug has received widespread global attention, particularly because President Donald Trump said he had taken it to prevent COVID-19.

In April, the Food and Drug Administration warned against using the drug outside of clinical trials or hospital settings, as it may lead to potentially deadly heart problems in some people.

Other studies of hydroxychloroquine are ongoing. However, some research has already found no benefit to the drug among COVID-19 patients. And a study published Wednesday in [The New England Journal of Medicine](#) found hydroxychloroquine was no better than a placebo at preventing coronavirus infection.

"We all entered this collaboration to contribute in good faith and at a time of great need during the COVID-19 pandemic," the study authors wrote in their retraction. "We deeply apologize to you, the editors and the journal readership for any embarrassment or inconvenience that this may have caused."

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